REMARKS

1. Status of the Claims

Claims 3, 6-8, 12, and, 21-22 are currently pending in the present application.

2. Rejection of Claims 3, 6-8, and 12 Under 35 U.S.C. § 102(b)

In the Office Action mailed April 14, 2004, (hereinafter the "Action"), the Examiner maintains the rejection of claims 3, 6-8, and 12 as being allegedly anticipated under 35 U.S.C. § 102(b) by Leturcq et al. (Journal of Cellular Biochemistry (1992) Supplement 16, Part C, Page 151, Abstract CB109). The present rejection is respectfully traversed for the reasons on record and the reasons discussed below.

A. Monoclonal Antibody 18G4

The Examiner asserts at the bottom of page 3 of the Action that Leturcq et al. allegedly teaches that three different epitope groups were elucidated and that 18G4 binds native LBP and the complex of LBP bound to LPS allegedly meeting the requirements of the claims.

Applicants respectfully submit that the Examiner mischaracterized the teachings of Leturcq et al. because Leturcq et al. never provides an enabling disclosure of the binding specificity of monoclonal antibody 18G4 to denatured LBP which is an element recited by independent claims 3, 6, 12, and 21. Therefore, the present rejection should be withdrawn because each and every claim element is not present and enabled by the cited reference.

The Examiner also asserts at the bottom of page 3 of the Action that the statement in Leturcq et al., "One (8C9) of the three

recognizes denatured LBP only" allegedly "means that the other two antibodies, 1E8 and 18G4, bind to more than just the denatured LBP". Applicants respectfully submit that the statement, "One (8C9) of the three recognizes denatured LBP only" does not clarify in an enabling manner whether or not monoclonal antibody 18G4 binds to denatured LBP. The Examiner has made an unsupported assertion that monoclonal antibodies 1E8 and 18G4 "bind to more than just the denatured LBP". Applicants again submit that the present rejection should be withdrawn because each and every claim element is not present and enabled by the cited reference.

The Examiner asserts in the first paragraph on page 4 of the Action that "Applicants have presented no scientific data stating that the 1E8 and 18G4 antibodies could not also bind denatured LBP". Applicants respectfully submit that "1E8" is not an element of the claimed invention and, therefore, the binding specificities of 1E8 are not relevant because the Examiner has not presented evidence that 1E8 has the claimed binding specificities. Regarding the Examiner's assertion that Applicants have presented no scientific data stating that monoclonal antibody 18G4 allegedly could not also bind denatured LBP, Applicants respectfully submit that the specification teaches the binding specificity of monoclonal antibody 18G4 to denatured LBP, for example, in Figure 4 of the specification.

At the top of page 5 of the Action, the Examiner asserts that monoclonal antibody 18G4, meets the claimed functional requirements, "as evidenced by its binding abilities, therefore Leturcq et al., [allegedly] meet[s] each and every limitation of the claims". Applicants respectfully submit that Leturcq et al. does not provide an enabling teaching of the binding specificity of monoclonal antibody "18G4" in Leturcq et al. to denatured LBP. Therefore, the present rejection should be withdrawn because each and every claim element is not present and enabled by Leturcq et al.

In the first full paragraph on page 5 of the Action the Examiner asserts that Leturcq et al. allegedly teaches monoclonal antibodies with the same functional abilities as those recited by the instant claims. Applications respectfully submit that in addition to not disclosing the binding specificity of monoclonal antibodies 1E8 and 18G4 to denatured LBP, Leturcq et al. also does not teach a monoclonal antibody that inhibits LBP-mediated LPS-dependent activation of myeloid cells (claim 7) and Leturcq et al. does not teach a monoclonal antibody that inhibits LBP-mediated LPS-dependent secretion of tumor necrosis factor from myeloid cells (claim 8). Therefore, the Examiner's statement that Leturcq et al. teaches monoclonal antibodies with the same functional abilities as those recited by the instant claims is without merit because Leturcq et al. does not provide an enabling teaching of the claimed functional characteristics.

On page 5 of the Action, the Examiner also asserts that, "The limitation that the monoclonal antibody include binding specificity to: LBP, denatured LBP, a complex containing LBP and LPS, and [of] Mab 4D7, Mab 5C5, Mab 6B6, Mab 8C9, Mab 18G4 or Mab 24B7 simply describes the binding specificity that the prior art antibody is capable of meeting". The courts have found that a reference relied upon to support a rejection under 35 U.S.C. § 102 must itself be an enabling disclosure under 35 U.S.C. § 112 (see, e.g., *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364,62 USPQ2d 1865 (Fed. Cir. 2002)). Thus, Applicants respectfully submit that the present rejection under 35 U.S.C. § 102 should be withdrawn because, as discussed above, the Leturcq et al. reference is not enabling under 35 U.S.C. § 112.

3. Rejection of Claims 21-22 Under 35 U.S.C. § 102(b)

At the top of page 6 of the Action, the Examiner maintains the

rejection of claims 21-22 as being allegedly anticipated under 35 U.S.C. § 102(b) by Leturcq et al. The present rejection is respectfully traversed for the reasons on record and the reasons discussed below.

First, a point of clarification, the Examiner asserts that, "claims 21-22 are ultimately dependant upon rejected claim 6". Applicants respectfully submit that claim 21, as currently pending, is an independent claim which recites all of the elements of claims 6 and 7.

Next, the Examiner asserts that, "there is nothing in the composition besides the antibodies, therefore the claims were rejected over Leturcq et al.". Regarding claim 21, Applicants respectfully submit that Leturcq et al. does not disclose a pharmaceutical composition comprising at least one dose of an immunotherapeutically effective amount of the monoclonal antibody of claim 7 in a pharmacological carrier. For example, Leturcq et al. does not disclose a pharmaceutical composition, an immunotherapeutically effective amount of a monoclonal antibody, or a pharmacological carrier. Therefore, the present rejection should be withdrawn because each and every claim element is not present and enabled by the cited reference.

Regarding claim 22, Leturcq et al. does not disclose, for example, a pharmaceutical composition, an immunotherapeutically effective amount of two or more different monoclonal antibodies, or a pharmacological carrier. Therefore, the present rejection should be withdrawn because each and every claim element is not present and enabled by the cited reference.

CONCLUSION

The Applicant respectfully requests that the Examiner enter the response herein, withdraw all claim rejections, and place the claims in condition for allowance.

The Examiner is requested to contact the representative for the Applicants, to discuss any questions or for clarification. If there are any further fees associated with this response, the Director is authorized to charge our Deposit Account No. 19-0962.

Respectfully submitted,

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Date

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